

Application Number 10/695,845
Response to Office Action mailed June 26, 2007

REMARKS

This Amendment is responsive to the Final Office Action dated June 26, 2007. Applicant has amended claims 17 and 36 for clarity. As a result, claims 17-20 and 36-44 remain pending.

Claim Rejection Under 35 U.S.C. § 103

In the Final Office Action, the Examiner rejected claims 17-20 and 36-42 under 35 U.S.C. 103(a) as being unpatentable over Sandmore et al. (US 6,059,760) in view of Jones et al. (US 5,843,050). Applicant respectfully traverses the rejection to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention(s).

Applicant notes that the Examiner has indicated that dependent claims 43-44 also stand rejected on the Office Action Summary page, and also on page 2 of the Office Action (in section "DETAILED ACTION"). However, the Examiner did not specifically include claims 43-44 within the list of claims that stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sandmore in view of Jones. Applicant respectfully requests clarification as to whether claims 43-44 stand rejected. If these claims stand rejected over Sandmore in view of Jones, Applicant traverses any such rejection, to the extent such rejection may be considered applicable to the claims as amended.

With reference to claims 17-20 and 36-42, Examiner argues that it is inherent and/or implicit in Sandmore that "the tubular structure on the top section has elastic restrictors that are fully capable and would change in size in response to a change in fluid flow (increase in fluid flow) which would provide a variable amount of fluid force restriction" (emphasis added).¹ The Examiner refers to openings 100 and/or 132 of Sandmore, and states that "the openings would be fully capable of all structural, functional, operational and spatial limitations" (emphasis added).² Applicant respectfully disagrees.

Applicant submits that it is neither inherent nor implicit in Sandmore to provide, on an end of a tip section of a catheter assembly, an elastic restrictor that, when operable, changes in

¹ Page 3, paragraph 3 of the Office Action.

² Page 4, first sentence of the Office Action.

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size in response to a change in fluid flow to provide a variable amount of fluid force restriction.

As stated in the MPEP, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.³ In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.⁴ Applicant submits that the Examiner has not provided such a basis in fact and/or technical reasoning to reasonably support a determination that an elastic restrictor, as recited in the claims, necessarily flows from the teachings of Sandmore. Instead, the Examiner has only alleged that the openings 100 and/or 132 are capable of changing in size.

Applicant first notes that fluid outlets 100 disclosed in Sandmore (and as shown in FIGS. 13-14, for example) are located on a sidewall 102 of the cannula tip 45'. This location is distinct from that of the elastic restrictor recited in the claims (as amended), which is located on an end of a tip section. Applicant further notes that the only opening on an end 104 of cannula tip 45' in Sandmore is opening 132 (shown in FIGS. 13-14). However, Sandmore states that the end 104 is a substantially closed distal end 104 that prevents fluid from exiting therethrough.⁵ Opening 132 is only a tiny aperture that is provided to prevent air from becoming entrapped in the distal end of cannula tip 45'.⁶ Because opening 132 of Sandmore allows only air to travel therethrough, it is neither inherent nor implicit within Sandmore to provide, on an end of a tip section of a catheter assembly, an elastic restrictor that, when operable, changes in size in response to a change in fluid flow to provide a variable amount of fluid force restriction.

In addition, Sandmore fails to disclose or suggest a catheter having, on a sidewall, one or more openings arranged such that forces resulting from fluid flow out of said openings and out of said elastic restrictor are substantially balanced, as required by claims 17-20 and 36-42. With regard to this particular claim element, the Examiner has referred to columns 8-9 of Sandmore. However, columns 8-9 of Sandmore make it clear that fluid exits out of fluid outlets 100. As

³ MPEP, section 2112.

⁴ Id.

⁵ Col. 8, lines 33-37 of Sandmore.

⁶ Id. See also FIG. 14 of Sandmore.

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noted above, only air travels through opening 132 of Sandmore. The fluid outlets 100 extend toward the proximal end 116 and reverse the flow of fluid exiting from the cannula tip 45'.⁷

Therefore, Applicant submits that Sandmore even teaches away from having one or more sidewall openings arranged such that forces resulting from fluid flow out of said openings and out of said elastic restrictor are substantially balanced, as required by claims 17-20 and 36-42. As previously outlined above, Sandmore does not teach or suggest an elastic restrictor on an end of cannula tip 45' that allows fluid to pass therethrough. Because fluid only exits out of the fluid outlets 100, and does not exit out of opening 132, Applicant submits that the forces resulting from fluid flow out of fluid outlets 100 cannot be substantially balanced. Although fluid outlets 100 of Sandmore are capable of reversing the flow of fluid, forces resulting from fluid flow out of these outlets 100 cannot be substantially balanced, because no fluid exits out of opening 132. Therefore, for at least these reasons, Sandmore does not teach or suggest each and every element of claims 17-20 and 36-42.

Applicant further submits that Jones does not overcome the shortcomings of Sandmore. Jones fails to disclose or suggest a catheter having, on a sidewall, one or more openings arranged such that forces resulting from fluid flow out of said openings and out of said elastic restrictor are substantially balanced, as required by claims 17-20 and 36-42. With regard to this particular claim element, the Examiner has referred to figures 5 and 7, along with lines 14-63 of column 11, of Jones. These portions of Jones disclose an aperture 88 on a distal segment 72. Aperture 88 accommodates a guidewire to pass therethrough.⁸ Aperture 88 permits the escape of pressurized media, such as contrast media or medication, sufficient to create a fluid flow in cavity 90.⁹ However, only a relatively small volume of fluid flows through aperture 88 to prevent stagnation in the vessel at the distal end of the catheter.¹⁰ Most of the fluid exiting distal segment 72 flows out of a plurality of lateral apertures 74.¹¹ Applicant submits that forces resulting from fluid flow out of said lateral apertures 74 and out of aperture 88 cannot be substantially balanced. Firstly, the majority of the fluid flows out of apertures 74, while only a minimal amount may exit

⁷ Col. 8, lines 11-13 of Sandmore.

⁸ Col. 11, lines 45-51 of Jones.

⁹ Col. 11, lines 38-40 of Jones.

¹⁰ See col. 10, lines 60-64 and col. 11, lines 21-22 of Jones.

¹¹ See, e.g., FIG. 5 of Jones.

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aperture 88. In addition, it appears from the disclosure of Jones that fluid exits out of apertures 74 in directions substantially perpendicular to the direction of the small flow of fluid out of aperture 88. In this case, it would not be possible for the forces resulting from fluid flow out of said lateral apertures 74 and out of aperture 88 to be substantially balanced.

Further, Applicant submits that Jones fails to disclose or suggest, on an end of a tip section of a catheter assembly, an elastic restrictor that, when operable, changes in size in response to a change in fluid flow to provide a variable amount of fluid force restriction, as required in claims 17-20 and 36-42. Jones discloses that aperture 88 may be constructed from a material having sufficient resilience to permit an elastic expansion of aperture 88 to accommodate a guidewire therethrough.¹² While aperture 88 may allow a small amount of fluid to flow therethrough, Jones does not disclose or suggest that aperture 88 comprises an elastic restrictor that, when operable, changes in size in response to a change in fluid flow to provide a variable amount of fluid force restriction. Nowhere does Jones disclose or suggest that aperture 88 is such an elastic restrictor that would change its size in response to a change in fluid flow, and that accordingly provides a variable amount of fluid force restriction. Therefore, for at least these reasons, Jones does not teach or suggest each and every element of claims 17-20 and 36-42.

Claims 43-44 depend directly on independent claims 17 and 36, respectively. For at least the reasons outlined above, Applicant submits that neither Sandmore nor Jones, alone or in combination, disclose or suggest each and every element of these dependent claims.

Therefore, for at least these reasons, Applicant respectfully submits that the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 17-20 and 36-44 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

¹² Col. 11, lines 48-51 of Jones.

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CONCLUSION

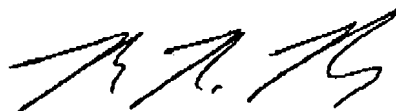
All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Although Applicant has focused the arguments above on specific claims, Applicant does not acquiesce to any of the rejections of dependent claims that are not specifically discussed. Applicant reserves further comment on any such claims, and reserves the right to present additional arguments on any of the pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

September 26, 2007

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